Dräger

K 003067

DEC 13 2000

Datei: Summary.RTF
Date:Aug 31, 2000
Author: Frank Clanzett

510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:
Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik GmbH,
Moislinger Allee 53-55
23542 Lübeck / Germany

APPLICANTS TELEPHONE NUMBER:
(01149)-451-882-3915

APPLICANTS FACSIMILE NUMBER:
(01149)-451-882-3915

APPLICANTS CONTACT PERSON IN THE USA:
Jim Brennan
Director Regulatory Affairs, Dräger Medical, Inc.
3135 Quarry Road
Telford, PA 18969
phone: 215-721-5400
fax: 215-723-5934

DATE THE SUMMARY WAS PREPARED:
January 08, 1997

DEVICE NAME:

Trade Name:	Caleo
Common Name:	Incubator
Classification Name:	Incubator, Neonatal

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Incubator 8000 - Manufactured by Dräger Medizintechnik, Lübeck, Germany and sold in the United States by Dräger Medical, Inc.

Omnibed - Manufactured by Ohmeda Medcal, USA

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DESCRIPTION OF THE DEVICE:

The incubator "Caleo" is used for premature and sick new born Babys which need specific controlled ambient condition. The Caleo is able to provide the controlled ambient conditions in its performance ranges like described in the user manual and as set by the user.

The Caleo distinguishes between two major modes.

1 Air Control Mode
In this mode the user sets the appropriate ambient air temperature, oxygen and if this option is installed the ambient humidity inside the incubator. The sensor system detects and measures the values in the incubator and the control system controls that the parameter set by the user are achieved.

2 Skin Control Mode
In this mode the user sets the desired patient temperature. A skin temperature probe transfers the measured value to the control system and the heating system of the incubator will increase or decrease the ambient temperature.

A humidity control unit to control also the humidity inside the incubator is available as an option.

INTENDED USE OF THE DEVICE CALEO:

Therapy system providing a controlled supply of warmth, humidity and O_2 enrichment in the patient capsule for premature babies and sick neonates up to a body weight of 5 kg or a body length of 55 cm (when treating twins, the total body weight is limited to 5 kg).

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SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES:

The Caleo Incubator is substantially equivalent to the predicate devices Incubator 8000 from Dräger and the Omnibed from Ohmeda.

All features of the Caleo are also covered by the predicate devices all devices have the same intended use. Also the performance characteristics from the Incubator 8000 and the Caleo are nearly the same.
The technical solutions implemented in the Caleo are similar to those of the predicate devices and do not lead to new safety or effectiveness issues.

The Caleo fulfils at least the same international standards as the predicate devices of Dräger and has been tested according to these standards. Therefore the Caleo is as safe and effective as the predicate devices.

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Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik GmbH, Germany

Sep. 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Drager Medizintechnik GMBH
C/O Mr. Jim Brennan
Director Regulatory Affairs
Drager Medical, Incorporated
3136 Quarry Road
Teleford, Pennsylvania 18969

Re: K003067
Trade Name: Caleo
Regulatory Class: II
Product Code: FMZ
Dated: September 22, 2000
Received: October 2, 2000

Dear Mr. Brennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~K003606~~ K003067 w mD

Device Name: Caleo

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Petra Aval
R&D neonatal care systems
Dräger Medizintechnik

Sep. 2000

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003067